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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/563,587

04/18/2006

Jean Krutmann

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3294

62836 7590 03/02/2010

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LOS ANGELES, CA 90013

EXAMINER

SIMMONS, CHRIS E

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

03/02/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/563,587	<b>Applicant(s)</b> KRUTMANN, JEAN	
	<b>Examiner</b> CHRIS E. SIMMONS	<b>Art Unit</b> 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,5,6 and 9-13 is/are pending in the application.
- 4a) Of the above claim(s) 1,2,5,11 and 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6,9,10 and 13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Applicants' arguments, filed 10/12/2009, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

#### ***Claim Rejections - 35 USC § 103***

Claims 6, 9, 10 and 13 stand rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/036915 ("Bucher") in view of Pichereau et al.

Regarding new claim 13, COPD is the disease being treated in the primary reference. COPD meets the requirements in claim 13.

In response to applicant's arguments, the recitation "for combating diseases caused by effects of suspended particulate on lung tissue and/or cardiovascular diseases related thereto" has not been given patentable weight because the recitation occurs in the preamble. The recitation merely recites the intended use of the device. The structural limitations are able to stand alone and are met by the references. See *MPEP 2111.02 [R-3] II*. Whether Bucher or Pichereau are concerned with a different disease is not at issue concerning the claims currently at hand. At issue is whether the device - not its intended use- is disclosed by the references.

Applicant argues that Bucher provides an extensive list of exemplary salts, sugars, sugar alcohols and other osmotically active compounds while Pichereau discloses that not all osmolytes have the same properties. Applicant asserts that

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because the number of osmotically active compounds is large, and osmolytic properties are different from one osmolyte to another, there is no reasonable expectation of success. Examiner does not find this assertion to be persuasive. Bucher discloses that the invention treats airway diseases by hydrating the airway by administering a non-absorbable, osmotically active compound such as a salt, sugar, sugar alcohol, organic osmolyte, or *other osmotically active compound* to an airway surface of the subject *in an amount effective to increase the volume of fluid* on the airway surface. The skilled artisan would understand from the reference that one function of an “osmolyte” is to increase the volume of fluid if administered in an effective amount. Applicant’s assertion about the different properties of osmolytes relies on the lack of osmolytic protection in *E. faecialis* provided by ectoine in the Pichereau reference. The examiner notes, however, that the lack of osmolytic protection is not necessarily due to a lack of ectoine’s ability to increase the volume of fluid, it is due to the inability of the bacterium to initially uptake the ectoine into its cell in order to utilize the osmoprotective properties of ectoine. Since the bacterium failed to uptake the compound, then it could not protect it.

Applicant also argues that since there is not a finite number of predictable solutions that can be applied to the preparation of an inhalation device, and thus the claims cannot be obvious under an “obvious to try” rationale. Examiner disagrees. The primary discloses that an increase in the volume of fluid in the airway can be used for treatment methods of the invention by administering an effective amount of an osmolyte. This disclosure provides one of ordinary skill in the art with a finite number of

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predictable solutions since one would only have to administer an effective amount of an osmolyte. The skilled artisan need only select a known osmolyte to administer as outlined in the primary reference. The secondary reference discloses that ectoine functions as an osmolyte. Accordingly, the skilled artisan is provided with the knowledge to practice the current invention as claimed.

No claims are allowable at this time.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRIS E. SIMMONS whose telephone number is

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(571)272-9065. The examiner can normally be reached on Monday - Friday from 7:30 - 5:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Chris E Simmons/  
Examiner, Art Unit 1612

/Frederick Krass/  
Supervisory Patent Examiner, Art Unit 1612